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Symptomatic efficacy of avocado/soybean unsaponifiables in the treatment of osteoarthritis of the knee and hip: a prospective, randomized, double-blind, placebo-controlled, multicenter clinical trial with a six-month treatment period and a two-month followup demonstrating a persistent effect.

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OBJECTIVE. To assess the efficacy and safety of avocado/soybean unsaponifiables (ASU) in the treatment of patients with symptomatic osteoarthritis (OA) of the knee or hip, as well as the potential residual effects of ASU after stopping treatment, to determine whether ASU might be a symptomatic slow-acting drug for the treatment of OA. **METHODS.** One hundred sixty-four patients with regular, painful, primary OA of the knee (n = 114) or hip (n = 50) entered a prospective, randomized, double-blind, placebo-controlled, parallel-group, multicenter trial with a 6-month treatment period and a 2-month posttreatment followup. A 15-day washout period for nonsteroidal antiinflammatory drugs (NSAIDs) preceded the study. Efficacy was judged according to 1) Lequesne's functional index (LFI) and 2) pain on Huskisson's visual analog scale (VAS; 100-mm scale), intake of NSAIDs/analgesics, and overall disability score (by 100-mm VAS). **RESULTS.** Eighty-five patients received ASU; 79 received placebo. One hundred forty-four patients were evaluable at month 6 (75 taking ASU; 69 taking placebo). The mean +/- SEM LFI score decreased from 9.7 +/- 0.3 to 6.8 +/- 0.4 in the ASU group and from 9.4 +/- 0.3 to 8.9 +/- 0.4 in the placebo group (P < 0.001 for intergroup difference at month 6). Pain decreased from 56.1 +/- 1.6 mm to 35.3 +/- 2.3 in the ASU group and from 56.1 +/- 1.8 mm to 45.7 +/- 2.6 in the placebo group (P = 0.003 at month 6). NSAID consumption was slightly lower in the ASU group. Fewer patients in the ASU group required NSAIDs (48%, versus 63% in the placebo group; P = 0.054). The success rate was 39% in the ASU group and 18% in the placebo group. Overall functional disability was significantly reduced in the ASU group. Improvement appeared more marked in patients with hip OA. A residual effect was observed at month 8. Tolerance was good to excellent for most patients. **CONCLUSION.** ASU treatment showed significant symptomatic efficacy over placebo in the treatment of OA, acting from month 2 and showing a persistent effect after the end of treatment.

Publication Types:

- Clinical Trial
- Multicenter Study

- Randomized Controlled Trial

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